



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1932d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

November 5, 2001

Our Reference: 2925551

Arthur Y. M. Chan, President
Art's Trading Company
830 – 7th Street
San Francisco, California 94107

WARNING LETTER

Dear Mr. Chan:

We inspected your seafood firm on September 27 and October 2, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP and GMP deviations. These deviations cause your Cuttlefish Roll and Fish & Shrimp Dumpling fishery products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the deviations on a Form FDA 483 and discussed them with Mrs. Amphorn Chan, Vice President, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious HACCP deviations are as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR

123.12(a)(2)(i). However, your firm does not have product specifications for the following:

- (a) Cuttlefish Rolls (from [REDACTED], to ensure control of the food safety hazards of potential pathogen growth and toxin formation as a result of time/temperature abuse, allergens, and metal inclusion in the product.
- (b) Fish & Shrimp Dumpling (from [REDACTED], to ensure control of the food safety hazards of pathogen growth and toxin formation as a result of time/temperature abuse, allergens, and metal inclusion in the product.

During the inspection, we also observed insanitary conditions that constitute good manufacturing practice (GMP) violations. These are as follows:

- (a) Birds were observed perching and roosting in the rafters and flying about the warehouse over food containers.
- (b) Bird droppings were observed throughout the warehouse, on the plastic wrapping of a 50-pound sack of rice, and on the floor below where the birds were perching.

You must immediately take appropriate steps to correct the deviations at your facility. We may initiate regulatory action without further notice if you do not correct them. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may detain your imported seafood products without examination.

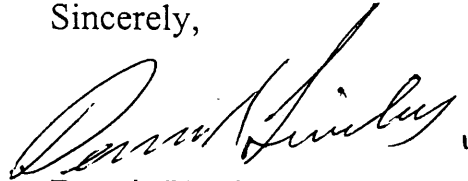
The above-identified deviations are not intended to be an inclusive list of deficiencies at your facility. For example, further review of your verification documents by the district, revealed that the continuing certificate issued by the [REDACTED] inspection authority to [REDACTED] the foreign manufacturer, had expired and the processor's HACCP plans for the Cuttlefish Roll and Fish & Shrimp Dumpling are not current. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Federal Food, Drug, and Cosmetic Act and all requirements of the federal regulations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. Your response should include copies of any available documentation demonstrating that corrections have been made. If you cannot complete all the

corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley", written in a cursive style.

Dennis K. Linsley
District Director
San Francisco District

Enclosure: FDA 483

cc: Mrs. Amphorn Chan, Vice President